K110671

510(k) SUMMARY

Winco Mfg., LLC
Stretchair Powered Wheeled Stretcher

APR 2 2 2011

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Winco, Inc.
5516 Southwest 1st Lane
Ocala, Florida 34474

Contact Person: James Ankoviak
President and CEO
Winco Mfg., LLC
5516 Southwest 1st Lane
Ocala, Florida 34474

Date Prepared: February 19, 2011

Name of Device and Name/Address of Sponsor

Winco Stretchair

Winco Mfg., LLC
5516 Southwest 1st Lane
Ocala, Florida 34474

Common or Usual Name

Stretcher

Classification Name

Stretcher, Wheeled, Powered

Predicate Device

TransMotion Medical, Inc. Power Drive Chair Model TMM6 (K091043)

Intended Use

The intended use of the Winco Stretchair is to provide a method of transporting patients within healthcare facilities.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Winco Mfg., LLC Stretchair is a battery powered device designed for use in healthcare facilities. Its intended function and use is to transport patients within the confines of the healthcare facility, where patient care is being administered. It can also be used to support the patient during examinations and other clinical activity which may take place in the facility.

The Stretchair can support a patient in either a supine (laying) position or seated position. The Stretchair model S300 is for patients weighing up to 300 lbs, the S675 is for patients weighing up to 675 lbs, and the S999 is for patients weighing up to 1000 lbs.

The product includes a battery powered linear actuator to lower the backrest and raise the footrest simultaneously. It also includes a hydraulic unit for vertical height adjustment.

B. Substantial Equivalence

The Winco Stretchair is substantially equivalent to the TransMotion Medical, Inc. Power Drive Chair Model TMM6 (K091043)

Performance Data

The Winco Stretchair has been tested to and meets the requirements of UL 60601-1 and CAN/CSA C 22.2 Electrical Safety Standards. The upholstery used meets the requirements of CAL 117 for Flame Retardancy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Winco, Inc.
% Mr. James Ankoviak
President and CEO
5516 Southwest 1st Lane
Ocala, Florida 34474

APR 2 2 2011

Re: K110671
Trade/Device Name: Winco Stretchair
Regulation Number: 21 CFR 890.3690
Regulation Name: Powered wheeled stretcher
Regulatory Class: Class II
Product Code: INK
Dated: February 25, 2011
Received: March 09, 2011

Dear Mr. Ankoviak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): TBD

Device Name: Winco Stretchair

Indications for Use:

The intended use of the Winco Stretchair is to provide a method of transporting patients within healthcare facilities.

Prescription Use ___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 801 Subpart C)

X(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110671